



TO: The Honorable Members of the Board of Regents

FROM: David H. Hamilton *David H. Hamilton*

SUBJECT: Proposed Addition of Sections 63.16 and 60.14, and Subdivision (d) to Section 64.5 of the Regulations of the Commissioner of Education Relating to Dispensing Self-Administered Hormonal Contraceptives

DATE: July 3, 2024

AUTHORIZATION(S): *Donna Bell*

SUMMARY

Issue for Decision (Consent)

Should the Board of Regents add sections 63.16 and 60.14, and subdivision (d) to section 64.5 of the Regulations of the Commissioner of Education relating to dispensing self-administered hormonal contraceptives?

Reason for Consideration

Required by State Statute (Chapter 128 of the Laws of 2023, as amended by Chapter 90 of the Laws of 2024).

Proposed Handling

The proposed amendment is submitted to the Full Board for adoption as a permanent rule at the July 2024 meeting. A copy of the proposed rule (Attachment A) is attached.

Procedural History

The proposed amendment was presented to the Professional Practice Committee for discussion at the February 2024 meeting of the Board of Regents. A Notice of Proposed Rule Making was published in the State Register on February 28, 2024, for a 60-day public comment period required under the State Administrative Procedure Act (SAPA).

Subsequently, Chapter 90 of the Laws of 2024 made this law retroactively effective on January 1, 2024. Therefore, emergency action was necessary at the March 2024 meeting to ensure that the proposed rule, which implements such Chapter, was in effect. A Notice of Emergency Adoption was published in the State Register on March 27, 2024.

Because the March 2024 emergency rule expired on June 9, 2024, a second emergency action was necessary at the May 2024 meeting to ensure that the emergency rule remained continuously in effect until it can be permanently adopted at the July 2024 Regents meeting. A Notice of Emergency Adoption was published in the State Register on June 26, 2024.

Following publication in the State Register, the Department received five comments on the proposed amendment. An Assessment of Public Comment (Attachment B) is attached. No changes to the proposed amendment are recommended at this time. A Notice of Adoption will be published in the State Register on July 31, 2024. Supporting materials are available upon request to the Secretary of the Board of Regents.

Background Information

Chapter 128 of the Laws of 2023, as amended by Chapter 90 of the Laws of 2024, (Chapter 128), effective January 1, 2024, amends the Education Law to allow New York State licensed pharmacists located within the State to dispense self-administered hormonal contraceptives to patients pursuant to non-patient specific orders written by the Commissioner of Health, licensed physicians, or certified nurse practitioners. Chapter 128 is intended to increase access to contraceptive drugs for patients in New York State.

Chapter 128:

- Amends section 6527 of the Education Law by adding a new subdivision (11), which permits a licensed physician to prescribe and order a non-patient specific order to a pharmacist licensed and located in this State, for the dispensing of self-administered hormonal contraceptives to patients, that are approved by the federal Food and Drug Administration (FDA).
- Amends section 6909 of the Education Law by adding a new subdivision (11), which permits a certified nurse practitioner to prescribe and order a non-patient specific order to a pharmacist licensed and located in this State, for dispensing self-administered hormonal contraceptives to patients, that are approved by the FDA.
- Amends section 6802 of the Education Law by adding a new subdivision (29) to define the term “self-administered hormonal contraceptives.”
- Amends section 6801 of the Education Law by adding a new subdivision (9) which provides that:
 - a) a pharmacist licensed and located in the State may execute a non-patient specific order for the dispensing of self-administered hormonal contraceptives that are prescribed or ordered by the Commissioner of Health, a New York State licensed physician, or New York State certified nurse practitioner;
 - b) prior to dispensing self-administered hormonal contraceptives to a patient, and at least every twelve months for returning patients, the

pharmacist must provide the patient with a self-screening risk assessment questionnaire, developed by the Commissioner of Health in consultation with the Commissioner of Education, to be reviewed by the pharmacist to identify any known risk factors and assist the patient's selection of an appropriate self-administered hormonal contraception. The pharmacist must also provide the patient with a fact sheet developed by the Commissioner of Health, that includes the clinical considerations and recommendations for use of the self-administered hormonal contraceptive, the appropriate method for using such hormonal contraceptive, information on the importance of follow-up health care, health care referral information, and the ability of the patient to opt out of practitioner reporting requirements;

- c) no pharmacist shall dispense self-administered hormonal contraception without receiving training satisfactory to the Commissioner of Education;
 - d) a pharmacist shall notify the patient's primary health care practitioner, unless the patient opts out of such notification, within seventy-two hours of dispensing the self-administered hormonal contraceptive. If the patient does not have a primary health care practitioner, or is unable to provide their contact information, the pharmacist shall provide the patient with a written record of contraceptives dispensed, and advise the patient to consult an appropriate health care practitioner; and
 - e) nothing shall prevent a pharmacist from refusing to dispense a non-patient specific order of a self-administered hormonal contraceptive if, in their professional judgment, potential adverse effects, interactions, or other therapeutic conditions could endanger the health of the patient.
- Adds a new section 267-a to the Public Health Law authorizing the Commissioner of Health to establish a non-patient specific order for dispensing self-administered hormonal contraceptives.
 - Authorizes that any addition, amendment, and/or repeal of any rule or regulation necessary for implementation may be made before the effective date.

Proposed Amendment

The proposed addition of section 63.16 of the Commissioner's regulations implements Chapter 128 for pharmacists by:

- adopting the definition of "self-administered hormonal contraceptives" as set forth in Chapter 128;
- establishing that a pharmacist licensed and located in New York State may execute a non-patient specific order to dispense self-administered hormonal contraceptives as set forth in sections 6527, 6801, and 6909 of the Education Law;
- setting forth the competency requirements for training deemed satisfactory to the Commissioner of Education;

- establishing the requirement that pharmacists dispensing self-administered hormonal contraceptives, pursuant to non-patient specific orders, maintain documentation of their successful completion of the training (such documentation shall be available for review by the Department upon request);
- establishing the standards, procedures, and reporting requirements for pharmacists located in New York State for dispensing self-administered hormonal contraceptives pursuant to a non-patient specific order; and
- establishing that nothing shall prevent a pharmacist from refusing to dispense a self-administered hormonal contraceptive to a patient, pursuant to a non-patient specific order, if in their professional judgment, potential adverse effects, interactions, or other therapeutic complications could endanger the health of the patient.

The proposed addition of section 60.14 of the Commissioner's regulations implements Chapter 128 for the practice of medicine by:

- adopting the definition of "self-administered hormonal contraceptives" as set forth in Chapter 128;
- establishing that a licensed physician may issue a written non-patient specific order and protocol for a licensed pharmacist located in this State to dispense self-administered hormonal contraceptives to patients in New York State; and
- setting forth the requirements for written non-patient specific orders and protocols for the dispensing of self-administered hormonal contraceptives issued by physicians.

Finally, the proposed amendments implement Chapter 128 for nursing by:

- adopting the definition of "self-administered hormonal contraceptives" as set forth in Chapter 128;
- establishing that a certified nurse practitioner may issue a written non-patient specific order and protocol for a licensed pharmacist located in this State to dispense self-administered hormonal contraceptives to patients in New York State; and
- setting forth the requirements for written non-patient specific orders and protocols for the dispensing of self-administered hormonal contraceptives issued by certified nurse practitioners.

Related Regents Items

May 2024: [Proposed Addition of Sections 63.16 and 60.14, and Subdivision \(d\) to Section 64.5 of the Regulations of the Commissioner of Education Relating to Dispensing Self-Administered Hormonal Contraceptive](https://www.regents.nysed.gov/sites/regents/files/524brca7.pdf)
(<https://www.regents.nysed.gov/sites/regents/files/524brca7.pdf>)

March 2024: [Proposed Addition of Sections 63.16 and 60.14, and Subdivision \(d\) to Section 64.5 of the Regulations of the Commissioner of Education Relating to Dispensing Self-Administered Hormonal Contraceptives](https://www.regents.nysed.gov/sites/regents/files/324brca10.pdf)

(<https://www.regents.nysed.gov/sites/regents/files/324brca10.pdf>)

February 2024: [Proposed Addition of Sections 63.16 and 60.14, and Subdivision \(d\) to Section 64.5 of the Regulations of the Commissioner of Education Relating to Dispensing Self-Administered Hormonal Contraceptives](https://www.regents.nysed.gov/sites/regents/files/224ppcd1.pdf)

(<https://www.regents.nysed.gov/sites/regents/files/224ppcd1.pdf>)

Recommendation

It is recommended that the Board of Regents take the following action:

VOTED: That sections 63.16 and 60.14, and subdivision (d) to section 64.5 of the Regulations of the Commissioner of Education be amended, as submitted, effective July 31, 2024.

Timetable for Implementation

If adopted as an emergency rule at the July 2024 Regents meeting, the proposed amendment will become effective as a permanent rule on July 31, 2024.

AMENDMENT TO THE REGULATIONS OF THE COMMISSIONER OF EDUCATION

Pursuant to sections 207, 6504, 6507, 6527, 6801, 6806, 6902 and 6909 of the Education Law and Chapter 128 of the Laws of 2023.

1. The Regulations of the Commissioner of Education are amended by adding a new section 63.16 to read as follows:

Section 63.16 Dispensing Self-Administered Hormonal Contraceptives

(a) Definitions. As used in this section, self-administered hormonal contraceptives, means self-administered contraceptive medications or devices approved by the federal Food and Drug Administration to prevent pregnancy by using hormones to regulate or prevent ovulation, and includes oral hormonal contraceptives, hormonal contraceptive vaginal rings and hormonal contraceptive patches.

(b) Pursuant to sections 6527, 6801, and 6909 of the Education Law, a pharmacist licensed and located in this state may execute a non-patient specific order to dispense self-administered hormonal contraceptives provided that:

(1) the pharmacist has successfully completed training in the dispensing of self-administered hormonal contraceptives, satisfactory to the commissioner;

(2) the non-patient specific order is prescribed or ordered by the commissioner of health, a physician licensed in this state, or a nurse practitioner certified in this state; and

(3) the self-administered hormonal contraceptive is approved by the federal Food and Drug Administration to prevent pregnancy by using hormones to regulate or prevent ovulation and includes oral hormonal contraceptives, hormonal contraceptive vaginal rings and hormonal contraceptive patches and is being dispensed to the patient for such purpose.

(c) Requirements.

(1) A pharmacist licensed and located in this state shall not dispense self-administered hormonal contraceptives to patients pursuant to a non-patient specific order without receiving training satisfactory to the commissioner. Training that is satisfactory to the commissioner shall entail the completion of instruction in the dispensing of self-administered hormonal contraceptives that provides:

(i) knowledge of the menstrual cycle, including the different menstrual cycle phases and hormonal functions;

(ii) knowledge of the various contraceptive methods, medications and devices, including both self-administered and non-self-administered contraceptives and devices. Such overview shall also include the pharmacology and mechanisms of actions for the various contraceptives and devices available on the market;

(iii) knowledge of the precautions and contraindications in the use of hormonal contraceptives; and

(iv) knowledge of the various techniques required to counsel and adequately screen patients for the dispensing of an appropriate self-administered hormonal contraceptive if applicable.

(2) Pharmacists that dispense self-administered hormonal contraceptives to patients pursuant to a non-patient specific order are required to maintain documentation of their successful completion of the training prescribed in paragraph (1) of this subdivision. Such documentation shall be available for review by the department upon request.

(d) Standards, procedures and reporting requirements for the dispensing of self-administered hormonal contraceptives pursuant to a non-patient specific order.

(1) Prior to dispensing self-administered hormonal contraceptives to a patient and at a minimum of every twelve months thereafter for each returning patient, the licensed pharmacist shall:

(i) Provide the patient with a self-screening risk assessment questionnaire, developed by the commissioner of health in consultation with the commissioner, to be reviewed by the pharmacist to identify any known risk factors and assist the patient's selection of an appropriate self-administered hormonal contraceptive; and

(ii) Provide the patient with a fact sheet, developed by the commissioner of health, that includes, but is not limited to, the clinical considerations and recommendations for use of the self-administered hormonal contraceptive, the appropriate method for using such self-administered hormonal contraceptive, information on the importance of follow-up health care, health care referral information, and the ability of the patient to opt out of practitioner reporting requirements.

(2) A licensed pharmacist shall notify the patient's primary health care practitioner, unless the patient opts out of such notification, within 72 hours of dispensing a self-administered hormonal contraceptive, that such self-administered hormonal contraceptive has been dispensed. Such notification may occur via electronic transmission or facsimile. If the patient does not have a primary health care practitioner or is unable to provide contact information for their primary health care practitioner, the pharmacist shall provide the patient with a written record of the self-administered hormonal contraceptives dispensed and advise the patient to consult an appropriate health care practitioner.

(3) A licensed pharmacist shall:

(i) maintain records of the dispensing of the self-administered hormonal contraception, in accordance with section 6810(5) of the Education Law; and

(ii) maintain or ensure the maintenance of a copy of the non-patient specific order which authorizes the pharmacist to dispense self-administered hormonal contraception in accordance with the requirements of this section.

(4) Nothing in this section shall prevent a pharmacist from refusing to dispense a non-patient specific order of self-administered hormonal pursuant to this section if, in their professional judgment, potential adverse effects, interactions or other therapeutic complications could endanger the health of the patient

2. The Regulations of the Commissioner of Education are amended by adding a new section 60.14 to read as follows:

Section 60.14 Non-patient specific orders to dispense self-administered hormonal contraceptives

(a) As used in this section, self-administered hormonal contraceptives means self-administered oral hormonal contraceptive medications or devices approved by the federal Food and Drug Administration to prevent pregnancy by using hormones to regulate or prevent ovulation, and includes oral hormonal contraceptives, hormonal contraceptive vaginal rings and hormonal contraceptive patches.

(b) A licensed physician may issue a written non-patient specific order and protocol for a licensed pharmacist to dispense self-administered hormonal contraceptives to patients in New York State, provided that the requirements of this section are met.

(c) Order and protocol.

(1) The non-patient specific order shall include, at a minimum, the following:

(i) the name, license number and signature of the licensed physician who issues the non-patient specific order and protocol;

(ii) the name and dose of the specific drug(s) or the name of specific medical device to be dispensed;

(iii) a protocol for dispensing the self-administered hormonal contraceptives or a specific reference to a separate written protocol for dispensing the self-administered hormonal contraceptives, which shall meet the requirements of paragraph (2) of subdivision (c) of this section.

(iv) the period of time that the order is effective, including the beginning and ending dates;

(v) a description of the group(s) of persons who may receive the dispensed self-administered hormonal contraceptives; and,

(vi) the name and license number of each licensed pharmacist authorized to execute the non-patient specific order and protocol or the name and address of the New York State licensed pharmacy that employs or contracts with the licensed pharmacist(s) to execute the non-patient specific order and protocol.

(2) The written protocol, incorporated into the order prescribed in paragraph (1) of subdivision (c) of this section shall, at a minimum, require the licensed pharmacist to:

(i) provide the patient with a self-screening risk assessment questionnaire, developed by the commissioner of health in consultation with the commissioner, to be reviewed by the pharmacist to identify any known risk factors and assist the patient's selection of an appropriate self-administered hormonal contraceptive;

(ii) provide the patient with a fact sheet, developed by the commissioner of health, that includes but is not limited to, the clinical considerations and recommendations for use of the self-administered hormonal contraceptive, the appropriate method for using such self-administered hormonal contraceptive, information on the importance of follow-

up health care, health care referral information, and the ability of the patient to opt out of practitioner reporting requirements;

(iii) notify the patient's primary health care practitioner, unless the patient opts out of such notification, within seventy-two hours of dispensing a self-administered hormonal contraceptive, that such self-administered hormonal contraceptive has been dispensed. Such notification may occur via electronic transmission or facsimile. If the patient does not have a primary health care practitioner or is unable to provide contact information for their primary health care practitioner, the pharmacist shall provide the patient with a written record of the self-administered hormonal contraceptives dispensed and advise the patient to consult an appropriate health care practitioner;

(iv) offer or provide in writing, the names and addresses of hospitals or other health providers that offer follow-up care, which shall be identified in the protocol; and

(vi) document the pharmacy services provided as described in this paragraph and maintain the documentation in accordance with sections 29.2(a)(3), 63.6(b)(7), and 63.6(b)(8) of this Title.

3. Section 64.5 of the Regulations of the Commissioner of Education is amended by adding a new subdivision (d) to read as follows:

(d) Non-patient specific orders to dispense self-administered hormonal contraceptives

(1) As used in this subdivision, self-administered hormonal contraceptives means self-administered oral hormonal contraceptive medications or devices approved by the federal Food and Drug Administration to prevent pregnancy by using hormones to regulate or prevent ovulation, and includes oral hormonal contraceptives, hormonal contraceptive vaginal rings and hormonal contraceptive patches.

(2) A certified nurse practitioner may issue a written non-patient specific order and protocol for a licensed pharmacist to dispense self-administered hormonal contraceptives, provided that the requirements of this subdivision are met.

(3) Order and protocol.

(i) The non-patient specific order shall include, at a minimum, the following:

(a) the name, license number and signature of the certified nurse practitioner who issues the non-patient specific order and protocol;

(b) the name and dose of the specific drug(s) or the name of specific medical device to be dispensed;

(c) a protocol for dispensing the self-administered hormonal contraceptives or a specific reference to a separate written protocol for dispensing the self-administered hormonal contraceptives, which shall meet the requirements of subparagraph (ii) of this paragraph;

(d) the period of time that the order is effective, including the beginning and ending dates;

(e) a description of the group(s) of persons who may receive the dispensed self-administered hormonal contraceptives; and,

(f) the name and license number of each licensed pharmacist authorized to execute the non-patient specific order and protocol or the name and address of the New York State licensed pharmacy that employs or contracts with the licensed pharmacist(s) to execute the non-patient specific order and protocol.

(ii) The written protocol, incorporated into the order prescribed in subparagraph (i) of this paragraph, shall, at a minimum, require the licensed pharmacist to:

(a) provide the patient with a self-screening risk assessment questionnaire, developed by the commissioner of health in consultation with the commissioner, to be

reviewed by the pharmacist to identify any known risk factors and assist the patient's selection of an appropriate self-administered hormonal contraceptive;

(b) provide the patient with a fact sheet, developed by the commissioner of health, that includes but is not limited to, the clinical considerations and recommendations for use of the self-administered hormonal contraceptive, the appropriate method for using such self-administered hormonal contraceptive, information on the importance of follow-up health care, health care referral information, and the ability of the patient to opt out of practitioner reporting requirement;

(c) notify the patient's primary health care practitioner, unless the patient opts out of such notification, within seventy-two hours of dispensing a self-administered hormonal contraceptive, that such self-administered hormonal contraceptive has been dispensed. Such notification may occur via electronic transmission or facsimile. If the patient does not have a primary health care practitioner or is unable to provide contact information for their primary health care practitioner, the pharmacist shall provide the patient with a written record of the self-administered hormonal contraceptives dispensed and advise the patient to consult an appropriate health care practitioner;

(d) offer or provide in writing, the names and addresses of hospitals or other health providers that offer follow-up care, which shall be identified in the protocol; and

(e) document the pharmacy services provided as described in this subparagraph and maintain the documentation in accordance with sections 29.2(a)(3), 63.6(b)(7), and 63.6(b)(8) of this Title.

ASSESSMENT OF PUBLIC COMMENT

Following the publication of a Notice of Emergency Adoption and Proposed Rule Making in the State Register on February 28, 2024, the State Education Department received the following comments on the proposed regulation:

1. COMMENT: A national reproductive and sexual health care organization and a New York City chapter of a national human rights association expressed support for the proposed rule to the extent that they augment accessibility to contraception.

DEPARTMENT RESPONSE: The comments were supportive. No changes are necessary.

2. COMMENT: Two national associations for physicians, two national reproductive and sexual health care organizations, and a New York City chapter of a national human rights association commented that pharmacists should be trained and required to verbally communicate to patients their right to opt out of provider notification.

DEPARTMENT RESPONSE: The proposed rule is consistent with the statute because when pharmacists provide patients with the required Department of Health (DOH) developed fact sheet, patients are advised that, among other things, they have the ability to opt out of practitioner notification. No changes are necessary.

3. COMMENT: A national association for physicians, two national reproductive and sexual health care organizations, and a New York City chapter of a national human rights association commented that the proposed rule should require additional training for pharmacists on the New York State Family Planning Benefit Program and information on the program should also be included within the documents that pharmacists are required to hand out to their patients.

DEPARTMENT RESPONSE: Training required under the proposed rule is consistent with the statute and sufficient for implementing the provisions of Chapter 128 of the Laws of 2023, as amended by Chapter 90 of the Laws of 2024 (Chapter 128). Additionally, after consultation with DOH, there are efforts underway to determine if this is a feasible option. This process will take time. When this process is completed, changes might be made to existing guidance and/or new guidance may be issued. However, the Department is obligated to amend its regulations to implement the statute as written. No changes to the proposed rule are necessary.

4. COMMENT: A national association for physicians, a national reproductive and sexual health care organization and a New York City chapter of a national human rights association commented that the training provided to pharmacists should be amended to include information on the need to keep a minor's use of contraception confidential.

DEPARTMENT RESPONSE: The proposed rule's training requirements are consistent with Chapter 128, and sufficient to both implement it and protect patients. Based on this comment, the Department consulted with DOH on this issue and was informed that DOH intends to release frequently asked questions (FAQs) for pharmacists with appropriate guidance. No changes to the proposed rule are necessary.

5. COMMENT: A national association for physicians commented that training programs for pharmacists should incorporate role-playing exercises and training on "cultural competencies."

DEPARTMENT RESPONSE: The proposed rule identifies the training that is sufficient for pharmacists to dispense hormonal contraceptives in the manner contemplated by Chapter 128. Varied instruction methods may be used to achieve the training outcomes contemplated by the statute. No changes to the proposed rule are necessary.

6. COMMENT: Two national reproductive and sexual health care organizations and a New York City chapter of a national human rights association commented that the regulations need to state that pharmacists are permitted to dispense hormonal contraception to minors without parental consent.

DEPARTMENT RESPONSE: Although Chapter 128 does not provide specific information regarding patient age, if the pharmacist believes the person has the capacity to understand the questions being asked, the ability to answer them, and can understand the instructions of how to take the medications and side effects, the pharmacist can dispense the hormonal contraceptive to the person. The Department has been advised that FAQs under development by DOH will address this question and a link to these FAQs will be provided on the Department website. No changes in the proposed rule are necessary.

7. COMMENT: A national association for physicians and a New York City chapter of a national human rights association commented that additional guidance and best practices on how to obtain informed consent from a minor need to be developed through training, amendment of the standing order, or amendment of the regulation.

DEPARTMENT RESPONSE: The proposed rule is consistent with the statute. No changes are necessary.

8. COMMENT: A national association for physicians commented that patients must be verbally informed that the service is confidential.

DEPARTMENT RESPONSE: Chapter 128 does not require that patients be verbally informed that the service is confidential. However, DOH's self-screening patient intake form includes language regarding patient confidentiality. No changes are necessary.

9. COMMENT: Two national associations for physicians stated that pharmacists should be required to inform patients (particularly minors) of the risk that confidential information may be disclosed to an insurer in connection with the dispensing of hormonal contraception.

DEPARTMENT RESPONSE: The proposed rule is designed to implement Chapter 128, which is silent on issues relating to disclosure and insurance matters. However, DOH advised the Department that it is developing FAQs on subjects like these. The Department website will provide links to such guidance once it is issued. No changes to the proposed rule are necessary.

10. COMMENT: A national association for physicians, a national reproductive and sexual health care organization, and a New York City chapter of a national human rights association commented that information must be provided to patients in their preferred language.

DEPARTMENT RESPONSE: Chapter 128 does not address any obligation to provide the information regarding the dispensing of hormonal contraceptives in any particular language(s). However, Education Law §6829 requires covered pharmacies, as defined in that section, to provide free, competent oral interpretation services to each individual with limited English proficiency who requests such services. DOH advised the Department that it is working on translations for forms and instructions that will be available to pharmacies. No changes to the proposed rule are necessary.

11. COMMENT: A national association for physicians commented that pharmacists should be required to advise their patients of the need to follow up with a health care provider within one to two months of starting the new hormonal contraceptive.

DEPARTMENT RESPONSE: The purpose of Chapter 128 is to increase access to hormonal contraceptives for patients who are unable to see a provider. Routine follow-ups are not a requirement for dispensing hormonal contraceptives. Thus, no changes are necessary.

12. COMMENT: A New York City chapter of a national human rights association commented that patients should be provided with a list of federally qualified health clinics, Title X clinics and other health practitioners in the area.

DEPARTMENT RESPONSE: The proposed rule is consistent with the statute. No changes are necessary.